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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies (TSE) Advisory Committee; Notice of Meeting

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AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies (TSE) Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 18, 2001, 8:30 a.m. to 5:30 p.m. and January 19, 2001, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 18, 2001, the committee will discuss whether recent information about new variant Creutzfeldt-Jakob disease (nvCJD) in France and bovine spongiform encephalopathy in France and other European countries suggests a need to reconsider FDA policies on suitability of blood donors who lived or traveled in those countries. In the afternoon, the committee will discuss the risks of Creutzfeldt-Jakob disease (CJD) and vCJD transmission by human cells, tissues

and cellular and tissue-based products intended for implantation, transplantation, infusion, or transfer that are currently or proposed to be regulated by FDA, and the possible deferral of donors who have resided in the United Kingdom. On January 19, 2001, the committee will discuss issues related to deer and elk infected with or exposed to chronic wasting disease in the United States and potential for human exposure. In the afternoon, the committee will discuss whether a history of possible exposure to various animal transmissible spongiform encephalopathy agents should be considered by FDA in determining suitability of blood donors.

Procedure: On January 18, 2001, from 8:30 a.m. to 5 p.m. and January 19, 2001, from 8:30 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 12, 2001. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 10:50 a.m., and 3 p.m. to 3:20 p.m. on January 18, 2001; and between 10:30 a.m. to 10:50 a.m., and 3 p.m. to 3:20 p.m. on January 19, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 12, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On January 18, 2001, from 5 p.m. to 5:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 12/18/00
December 18, 2000.

Linda A. Suydam
Linda A. Suydam,
Senior Associate Commissioner.

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Lynette N. Reese